WE CLAIM:

1. A drug delivery system for oral administration in humans for the controlled release of pravastatin comprising:

   (a) a core comprising a therapeutically effective amount of pravastatin or its pharmaceutically acceptable salts and a water swellable polymer;

   (b) an inert subcoating surrounding the core comprising at least one film forming polymer; and

   (c) a coating of an enteric polymer over said subcoating;

   such that the system provides enhanced stability in the acidic environment of the stomach and exhibits controlled release of the drug.

2. The drug delivery system according to claim 1 wherein pravastatin or its pharmaceutically acceptable salts comprises from about 5% to about 25% by weight of the total weight of the composition.

3. The drug delivery system according to claim 1 wherein said water swellable polymer is selected from the group consisting of pyrrolidone, cellulose ether, acrylic polymer, natural gum, and mixtures thereof.

4. The drug delivery system according to claim 3 wherein the pyrrolidone is polyvinylpyrrolidone.

5. The drug delivery system according to claim 3 wherein the cellulose ether is selected from the group consisting of hydroxypropyl cellulose, hydroxypropyl methylcellulose, hydroxyethyl cellulose, methylcellulose,

hydroxyethyl methylcellulose, hydroxypropyl, ethylcellulose, carboxymethyl cellulose, sodium carboxymethyl cellulose, hydroxycellulose, and mixtures thereof.

6. The drug delivery system according to claim 3 wherein the acrylic polymer is selected from the group consisting of methacrylates, polyacrylates copolymers, and mixtures thereof.

7. The drug delivery system according to claim 3 wherein the natural gum is selected from the group consisting of xanthan gum, karaya gum, locust bean gum, guar gum, gelan gum, gum arabic, tragacanth, carrageenan, pectin, agar, alginic acid, sodium alginate, and mixtures thereof.

8. The drug delivery system according to claim 1 wherein the water swellable polymer comprises from about 5% to about 40% by weight of the total weight of the composition.

9. The drug delivery system according to claim 8 wherein the water swellable polymer comprises from about 5% to about 25% by weight of the total weight of the composition.

10. The drug delivery system according to claim 1 wherein the core further comprises swelling agents.

11. The drug delivery system according to claim 10 wherein the swelling agent comprises a superdisintegrant.

12. The drug delivery system according to claim 11 wherein the swelling agent is selected from the group consisting of cross-linked polyvinylpyrrolidone, cross-linked sodium carboxymethyl cellulose, sodium starch glycolate, and mixtures thereof.

13. The drug delivery system according to claim 10 wherein the swelling agent comprises from about 5% to about 30% by weight of the total weight of the composition.

14. The drug delivery system according to claim 10 wherein the core further comprises diluents, binder, glidant, anti-adherent, lubricant, or mixtures thereof.

15. The drug delivery system according to claim 1 wherein the subcoat comprising a film forming polymer is selected from the group consisting of polyethylene glycol, polyvinylpyrrolidone, polyvinyl alcohol, hydroxypropyl cellulose, methylcellulose, ethyl cellulose, hydroxymethyl cellulose, hydroxypropyl methylcellulose, polyvinyl acetal diethylaminoacetate, and mixtures thereof.

16. The drug delivery system according to claim 1 wherein the enteric polymer is selected from the group consisting of cellulose acetate phthalate, hydroxypropyl methylcellulose phthalate, polyvinyl acetate phthalate, carboxymethyl ethylcellulose, co-polymerized methacrylic acid/methacrylic acid methyl esters and mixtures thereof.

17. The drug delivery system according to claim 1 wherein the subcoating and/or enteric coating may further comprise plasticizer, anti-adherent, colorant, and mixtures thereof.

18. A drug delivery system for oral administration in humans for the biphasic release of pravastatin comprising :

(a) a core comprising therapeutically effective amount of pravastatin or its pharmaceutically acceptable salts and a water swellable polymer;

(b) an inert subcoating surrounding the core comprising at least one film forming polymer;

(c) a coating of an enteric polymer over said subcoat;

(d) an overcoat of pravastatin or its pharmaceutically acceptable salts over the enteric coat; and

(e) a coating of an enteric polymer over said drug overcoat;

such that the system exhibits a biphasic release profile having an immediate release and controlled release phases.

19. The drug delivery system according to claims 1 or 18 wherein the dosage form being formed into a physical form selected from the group consisting of pellets, beads, granules, tablets and capsules.

20. The drug delivery system according to claim 19 wherein the capsule shell is made of gelatin, hydroxypropyl methylcellulose or starch.

21. The drug delivery system according to claim 19 wherein tablet dosage forms further comprises coating with a fast dissolving film of a water soluble polymer.

22. A drug delivery system for oral administration in humans for the controlled release of pravastatin comprising pravastatin or its pharmaceutically acceptable salts wherein the drug delivery system exhibits the following *in*

vitro dissolution profile when measured in a type 1 dissolution apparatus according to U.S. Pharmacopoeia XXII in pH 6.8 phosphate buffer media at 50 rpm:

(a) more than 20% of the total pravastatin is released within 1 hour of measurement in said apparatus;

(b) more than 50% of the total pravastatin is released within 3 hours of measurement in said apparatus; and

(c) more than 70% of the total pravastatin is released within about 4-6 hours of measurement in said apparatus.